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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,810	11/17/2003	Shengwen Li	ALLE0004-100 (17614(BOT))	5198
34132	7590	09/20/2005	EXAMINER	
COZEN O'CONNOR, P.C. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER

1656

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/715,810	Applicant(s) LI ET AL.	
	Examiner Chih-Min Kam	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,5-7,9-11,18-21,73 and 74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5-7,9-11,18-21,73 and 74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/17/03&5/12/04 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1, 5-7, 9-11, 18-21, 73 and 74 are pending.

Applicants' amendment filed June 29, 2005 is acknowledged. Applicants' response has been fully considered. Claims 1, 5-7, 9 and 10 have been amended, claims 2-4, 12-17 and 22-72 have been cancelled, and new claims 73 and 74 have been added. Therefore, claims 1, 5-7, 9-11, 18-21, 73 and 74 are examined.

### **Withdrawn Claim Rejections-Obviousness Type Double Patenting**

2. The previous rejection of claims 1, 2, 20 and 21 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 10 of U. S. Patent 6,203,794 is withdrawn in view of applicants' amendment to the claims and applicants' cancellation of the claim in the amendment filed June 29, 2005.

### **Withdrawn Claim Rejections - 35 USC § 112**

3. The previous rejection of claims 1, 2, 6-11 and 18-21, under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicants' amendment to the claim, applicants' cancellation of the claim and applicant's response at pages 5-7 in the amendment filed June 29, 2005.
4. The previous rejection of claims 2 and 8, under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' cancellation of the claim in the amendment filed June 29, 2005.

### **Withdrawn Claim Rejections - 35 USC § 102**

5. The previous rejection of claims 1, 2, 20 and 21, under 35 U.S.C. 102(b) as anticipated by Dolly *et al.* (U.S. Patent 6,203,794), is withdrawn in view of applicants' amendment to the claim,

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applicants' cancellation of the claim and applicant's response at page 8 in the amendment filed June 29, 2005.

6. The previous rejection of claims 1, 20 and 21, under 35 U.S.C. 102(b) as anticipated by Lisk *et al.* (WO 2002/089834), is withdrawn in view of applicants' amendment to the claim, and applicant's response at page 8 in the amendment filed June 29, 2005.

**Maintained-Informalities**

The disclosure is objected to because of the following informalities:

7. Fig. 2 is objected to because the drawing recites the peptide sequence of SEQ ID NO:5 being SEQ ID NO:39, which is not correct. Appropriate correction is required.

8. The specification recites amino acid and nucleotide sequences at pages 25 (e.g., tetrapeptides), 26, 37 and 38, however, there are no sequence identifiers "SEQ ID NO:" provided. Applicants must comply with the requirements of the sequence rules (37 CFR 1.821-1.825) and provide a new copy of sequence listing and CRF containing all the sequences.

**Response to Arguments**

Applicants indicate they will submit a revised sequence listing and a revised Fig. 2 in the later date to address this matter. Thus, the objection is maintained until the correction is made.

**New Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1, 5-7, 9-11, 18-21, 73 and 74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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10. Claims 1, 5-7, 9-11, 18-21, 73 and 74 are indefinite because the claim lack essential steps in the method treating a botulinum toxin intoxication. The missing steps are an effective amount of a glycosylated inactive botulinum toxin administered, and the outcome of the treatment. Claims 5-7, 9-11 and 18-21 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

*Response to Arguments*

Applicants indicate claims have been amended to delete the phrase “an effective amount of at least one rescue agent” to avoid the rejection as being indefinite. However, an effective amount of a glycosylated inactive botulinum toxin is required for practicing the claimed method, thus the claims are rejected under 35 U.S.C. 112, second paragraph as indicated in the section above.

11. Claims 18-21 recite the limitation "rescue agent" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Conclusion***

12. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

CMK

September 10, 2005

  
KATHLEEN M. KERR, PH.D.  
SUPERVISORY PATENT EXAMINER